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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
TRAN, SUSAN T	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 14

Application Number: 10/073,978
Filing Date: February 14, 2002
Appellant(s): HASSEN, KEN

Vincent K. Shier
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/29/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-14 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,602,039	Cavazza	07-1986
6,063,820	Cavazza	05-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavazza U.S. 4,602,039 (I), in view of Cavazza US 6,063,820 (II).

Cavazza '039 teaches pharmaceutical composition in the form of tablet or capsule comprising salts of L-carnitine and salts of alkanoyl L-carnitine (see abstract, and claims 1-2). Cavazza '039 also teaches non-hygroscopic salts of L-carnitine as the active agent, which further comprises pharmaceutically acceptable excipients (column 7, lines 29-55). The methods of preparation are disclosed in examples 1-10.

Cavazza '039 does not teach the L-carnitine further comprising hydroxycitric acid, co-enzyme Q10, chromium picolinate, gamma linolenic acid, resveratrol, omega-3 acids, an antioxidant, or a vitamin.

Cavazza '820 teaches pharmaceutical composition comprising alkanoyl L-carnitine or pharmaceutically acceptable salt thereof, and gamma linolenic acid or salt thereof (column 2, lines 27-49). The composition may further comprises vitamins, co-enzymes, co-enzyme Q10, and antioxidants (columns 2-3). Thus, it would have been obvious for one of ordinary skill in the art to combine the teachings of '039 and the '820 by including additional ingredients such as gamma linolenic acid, vitamins, co-enzymes, and/or antioxidants into a pharmaceutical composition comprising hygroscopic salts of l-carnitine and alkanoyl L-carnitine with the expectation of at least similar result.

The examiner notes that the cited references do not teach the claimed particle sieve size, however, because they teach the crystallization of L-carnitine salts, and the manufacture of solid dosage forms using the crystallized product, the burden is shifted to the applicant to show criticality in the specific particle sieve size claimed.

(11) Response to Argument

Appellant argues that both, Cavazza I and Cavazza II do not teach the claimed particle size of L-carnitine. However, the claimed particle size has not been shown to provide unexpected results. Appellant's Declaration filed 03/31/03, states that the fineness of the particle size, as well as the particle size range of ultra-fine L-carnitine, provides an ideal physical form to ensure content uniformity when filling multi-component active products in two-piece hard gelatin capsules. Cavazza I teaches the use of L-carnitine that is useful in pharmaceutical compositions, namely, tablets and capsules (column 7, lines 29-47). The ability to use smaller particle size to fill the spaces formed by larger particle size (if used) is not unexpected or unusual, and is

recognized by one of ordinary skill in the art. Furthermore, particle size is a parameter that is routinely determine by formulation chemist, and therefore, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine suitable particle size of L-carnitine depending on the desire dosage form since Cavazza I also teaches the use of L-carnitine in a capsule.

Appellant's Declaration filed 03/31/03 has been fully considered but is not persuasive because the Declaration is not commensurate with the scope of the present claims. Declaration addresses ultrafine L-carnitine soft gel dosage form in combination with 1) omega-3 fatty acids in fish oil, 2) coenzyme Q10, and 3) alpha lipoic acid (see paragraph 12). This is not the scope of any of the claims presented. Furthermore, appellant has not provided any side by side comparative data establishing a criticality of the particle size. Declaration refers to the production of soft gel capsule. Cavazza I suggests the production of tablet and capsule.

Appellant argues that the capsules do not exhibit premature moisture pickup. Cavazza recognized that the salts of the L-carnitine are not hydroscopic, and therefore, suitable for the manufacture of pharmaceutically acceptable dosages. No comparison data of the degree of the lack of moisture pickup over a unit time against this teaching.

With regard to the claimed benefit with physical-chemical stability, Cavazza II recognized the present of vitamin E and capsule to improve membrane stability (column 4, lines 11-14). It is not necessary that the prior art recognize each and every advantageous result that accrue from a limitation in the claims. Therefore, appellant

showing of beneficial results are not persuasive since the prior art teaches same advantageous results.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

S. Tran

October 28, 2003

Conferees
Thurman K. Page

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

~~James Spear~~

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VA 22202